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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/284,935 06/01/99 TAKEBE

M 211A-2828-PC

EXAMINER

HM12/0622

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AFREMOVA, V

ART UNIT

PAPER NUMBER

1651

DATE MAILED:

06/22/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.
09/284,935

Applicant(s)
Takebe et al.

Examiner
Vera Afremova

Art Unit
1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 17, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4, 5, and 7 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 5, and 7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other: _____

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DETAILED ACTION

Continued Prosecution Application

The request filed on 4/17/2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/284,935 is acceptable and a CPA has been established. An action on the CPA follows.

Claims 1, 2, 4, 5 and 7 as amended (Paper No. 13 filed 1/17/2001) are pending and under examination.

Claims 3, 6 and 8 were canceled by applicants in the Paper No. 13 filed 4/17/2001.

Claim Rejections - 35 U.S.C. § 112

Indefinite

Claims 2 and 4 as amended are rejected under 35 U.S.C. 112, *second paragraph*, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is rendered indefinite by the phrase “and resistant starch becoming a nutrient of lactic bacteria”. It is unclear as claimed whether this “resistant starch” (claim 2, line 12) is an intermediate product which is obtained during hydrolysis of grains by koji mold or whether this “resistant starch” is an additional component in “a mixture” (claim 2, lines 2) which is independent from koji mold fermentation. It is uncertain what subject matter is intended for the invention of the claim 2. Is it a product obtained by a method of making the product? Is it a method of using a product which is obtained by a method of making the product? With regard to

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“lactic bacteria” (claim 2, line 12) it is uncertain whether these lactic bacteria the same as or different from “beneficial microorganisms” which are lactic bacteria (see claim 4, for example).

content in the whole composition during this step?

Claim 2 as amended remains indefinite because it is unclear what is “resistant” starch or what makes starch to be “resistant”. How to select a “resistant” starch? Would be any difference between the claimed resistant starch and starch as inert absorbent in therapeutic composition?

Claim Rejections - 35 U.S.C. § 102/103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2, 4, 5 and 7 as amended are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over US 4,308,284 [A] in the light of teaching by US 5,885,632 [B] or JP 7-23725 [N] and in the light of teaching by US 5,118,626 [C].

The claims 1 and 5 are directed to a method and to a composition obtained by the method comprising step of inoculating grains with koji mold in order to obtain a koji mold preparation resultant, step of adding water to the resultant in order to hydrolyze proteins and saccharides contained in the resultant wherein the resultant contains beneficial microorganisms or wherein

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beneficial microorganisms were added to the resultant and wherein koji mold and beneficial microorganisms are cultivated together in the resultant and step of removing phytic acid from the grains. The claim 2 is further drawn to the presence of starch in the composition. The claims 4 and 7 are further drawn to beneficial microorganisms such as lactic bacteria and/or *Eumycetes* (yeasts) in the composition and in the method for making the composition.

US 4,308,284 [A] clearly teaches a process and a product obtained by the process comprising steps of inoculating grains with koji mold, adding water and adding beneficial microorganisms such as yeasts or lactic acid bacteria (abstract; col. 7, lines 5-30; col.3, lines 61-64; col.4, lines 44-46; col.5, line 21). The step of removing phytic acid which is contained in the grains or hydrolyzed resultant is inherently present in the method/composition-obtained-by-method of the cited patent '284 in the light of teaching by US 5,885,632 [B] or JP 7-23725 [N]. For example: the teaching of US 5,885,632 [B] demonstrates that koji molds have high phytase which are enzymes decomposing phytic acid and phytic acid is removed in the presence of added water during koji mold hydrolysis (see US'632 col. 9, lines 15 and col.8, lines 60-67). And the presently claimed method and composition-obtained-by-method are encompassing the use of identical koji molds, the use of identical grains/resultants and the use of additional water as it is taught by US 5,885,632. Therefore, the step of removing phytic acid appears to be inherently present in the method and composition-obtained-by-methods are directed to the use of identical koji molds and grains as claimed and as disclosed. The teaching of JP 7-23725 [N] is similar to US 5,885,632 [B] (see English abstract).

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Further, with regard to the claim 2 which is drawn to the presence of starch or "resistant starch becoming a nutrient of lactic acid bacteria" the teaching of US 5,118, 626 [C] demonstrate that this feature as claimed is an inherent event. For example: during fermentation of grains by koji mold and lactic acid bacteria the starch is progressively becoming converted to products which are nutrients for lactic bacteria as taught by 5,118, 626 [C] (see col. 1, lines 15-21).

Therefore, the cited reference [A] discloses a method and a composition-obtained-by-method which appear to be identical to the presently claimed invention as explained above. Consequently, the claimed invention appears to be anticipated by the reference [A].

In the alternative, even if the claimed method and the claimed composition-obtained-by-method are not identical to the referenced method/composition with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced composition/method are likely to inherently possess the same characteristics of the claimed composition/method particularly in view of the similar characteristics which they have been shown to share such as the use of identical components and procedures as claimed in the light of teaching by US 5,885,632 [B] or JP 7-23725 [N] and in the light of teaching by US 5,118,626 [C]. Thus the claimed invention would have been obvious to those skilled in the art within the meaning of U.S.C. 103.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the references, especially in the absence of evidence to the contrary.

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Claim Rejections - 35 U.S.C. § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2, 4, 5 and 7 as amended are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,308,284 [A] in the light of teaching by US 5,885,632 [B] or JP 7-23725 [N] and in the light of teaching by US 5,118,626 [C] as applied to claims 1, 4, 5 and 7 above, and further in view of Remington [U], Merck [V] and JP 3-19686 [O].

Claims 1, 4, 5 and 7 as explained above. The claim 2 is further drawn to incorporation of additional starch into the composition.

The teaching of the cited references US 4,308,284 [A], US 5,885,632 [B], JP 7-23725 [N] and US 5,118,626 [C] is relied upon as explained above. The cited references are lacking a particular disclosure of incorporation of additional starch into a final fermentation product.

The secondary references Remington [U] or Merck [V] teach starch as inert absorbent for any pharmaceutical preparations or suitable for food industry.

Additional secondary reference JP- 3-19686 [O] is relied upon to demonstrate that a material obtained from grains fermented with koji molds is useful for promoting grow of lactic bacteria during fermentation of food products.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to use a product obtained after grain fermentation with koji molds for proliferation of lactic bacteria with a reasonable expectation of success in promoting

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growth of lactic bacteria since the similar use have been taught or suggested in the prior art for lactic bacteria in milk fermentation [O]. Further, the addition of starch to a final active material or to a fermented material intended for food or pharmaceutical products is known in the art [U, V]. Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary. The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351. The examiner can normally be reached on Monday to Friday from 9:00 to 5:30.

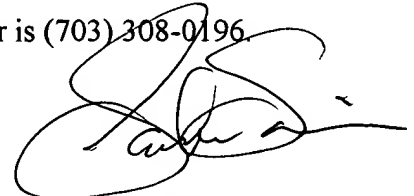
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vera Afremova,

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June 22, 2001.



SANDRA E. SAUCIER
PRIMARY EXAMINER